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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,235	12/18/2001	Michael A. Murphy	1865.1-4	9798
24243	7590	02/10/2006	EXAMINER	
CHARMASSON, BUCHACA & LEACH, LLP 1545 HOTEL CIRCLE SOUTH, SUITE 150 SAN DIEGO, CA 92108-3426			WEBMAN, EDWARD J	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/017,235	Applicant(s) MURPHY ET AL.	
	Examiner Edward J. Webman	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9, 14-17, 25, 29, 38, 44-61 and 65-107 is/are pending in the application.
- 4a) Of the above claim(s) 4-9, 14-17, 25, 29, 38, 44-61, 66-73, 79-89, 96 and 98-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 65, 74-78, 90-95, 97, 106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 2-9, 14-17, 25, 29, 38, 44-61, 65-107 remain pending. Claims 4-9, 14-17, 25, 29, 38, 44-61, 66-73, 79-89, 96, 98-105, 107 remain withdrawn from consideration. The elected polyamine remains the macrocyclic polyamine of claim 3 with R1-R4 = – (CH₂CH₂)_n with n=3-6 and the elected disease remains diabetes.

Claims 2, 3, 65, 74-78, 90-95, 97, 106 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Applicants claim a treatment of diabetes but provide no experimental evidence of efficacy, but rather a discussion of the literature on pages 14-21 and a recitation of merely hypothetical benefits to the treatment on pages 62-65. Applicants point to experimental data in US patent 5,906,996, however, that data concerns the non-elected Parkinson's disease. In particular, no tests on animal models to demonstrate effectiveness in humans is provided. Absent a demonstration, one of ordinary skill would not find the claimed treatment credible on its face, given the uncertainty of the fate of the claimed compounds in vivo.

Claims 2, 3, 65, 74-78, 90-95, 97, 106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because the claimed invention lacks patentable utility, the specification cannot be enabled for the elected treatment. Further, applicants provide no modality for treatment. That is, it is unclear as to how and where the

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treatment is to be delivered. With regard to the Wands factors: The nature of the invention is complex in view of the many parameters influencing the onset of diabetes, as disclosed on pages 14-21, therefore, the burden upon one of ordinary skill to determine an efficacious treatment will be high. The breadth of the claims is wide in view of the many different aspects of polyamine treatment disclosed on pages 62-65. The guidance of the specification is minimal; there is no suggestion of loci of treatment, delivery vehicles, nor dosage regimens. There are no working examples directed to the claimed treatment. The state of the art regarding diabetes treatment is low given that there is no cure known for the disease. Given the low state of the art and the plethora of parameters affecting the onset the disease, the predictability of the art is low, thus, one of ordinary skill would not routinely determine the parameters of efficacious treatment. Because the determination of a efficacious treatment parameters is not routine, the amount of experimentation necessary will be high.

Applicants response filed 10/2/05 outlines a general regime for selecting, testing and delivering an active agent to treat a disease. However, applicants provide no experimental data demonstrating efficacy. Applicants instead appear to infer that one of ordinary skill can use the regime applicants outline to predict efficacy and determine optimum treatment regimes and delivery vehicles. However, even the layman recognizes the unpredictability of the pharmaceutical art, as demonstrated by drugs recently removed from the market because their side-effects outweighed their usefulness.

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



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